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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,947	02/02/2000	Timothy P. Coleman	05270001AA	5493

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EXAMINER

LI, QIAN J

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/09/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/495,947

Applicant(s)

COLEMAN ET AL.

Examiner

Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>detailed action</i> . |

DETAILED ACTION

The Reply and Amendment filed on January 23, 2001 has been entered as Paper # 17. The examiner assigned to examine the application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Q. Janice Li, at Group Art Unit 1632.

Claims 1, 2, 14, 17, 21, and 24 have been amended, and claims 1-29 are pending. Upon reviewing of the instant application, the first Office action on merit is withdrawn in favor of restriction. The basis for such practice could be found in MPEP, 37 CFR 1.142 (a), which recites, "If TWO OR MORE INDEPENDENT AND DISTINCT INVENTIONS ARE CLAIMED IN A SINGLE APPLICATION, THE EXAMINER IN AN OFFICE ACTION WILL REQUIRE THE APPLICANT IN THE REPLY TO THAT ACTION TO ELECT AN INVENTION TO WHICH THE CLAIMS WILL BE RESTRICTED, THIS OFFICIAL ACTION BEING CALLED A REQUIREMENT FOR RESTRICTION (ALSO KNOWN AS A REQUIREMENT FOR DIVISION). SUCH REQUIREMENT WILL NORMALLY BE MADE BEFORE ANY ACTION ON THE MERITS; HOWEVER, IT MAY BE MADE AT **ANY TIME** BEFORE FINAL ACTION".

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-3, 10-13, 21, 23-25, and 27 are drawn to a composition comprising a plurality of recombinant nucleocapsid protein monomers, the primary sequence of which is derived from duck hepatitis B virus (DHBV), wherein the

- composition comprises a first and a second protein hapten. Classified in class 530, subclass 350.
- II. Claims 1-11, 24, 25, and 28 are drawn to a composition comprising a plurality of recombinant nucleocapsid protein monomers, the primary sequence of which is derived from DHBV, wherein the composition further comprises a nucleic acid sequence. Classified in class 536, subclass 23.1.
- III. Claims 24-26 are drawn to a composition comprising duck HBcAg and a hapten being linked to said DHBcAG, wherein said hapten is a carbohydrate. Classified in class 530, subclass 395.
- IV. Claims 24, 25, and 29 are drawn to a composition comprising duck HBcAg and a hapten being linked to said DHBcAG, wherein said hapten is a lipid. Classified in class 530, subclass 403.
- V. Claims 14-16 and 22 are drawn to an *in vivo* method of delivering nucleic acids to a subject in need thereof comprising administering to said subject a nucleic acid and a plurality of recombinant nucleocapsid protein monomers. Classified in class 514, subclass 44.
- VI. Claims 21, 23, and 24 are drawn to an *in vivo* method for eliciting an immunogenic response in a patient in need thereof comprising administering to said patient an effective amount of a composition comprising a plurality of recombinant nucleocapsid monomers derived from DHBV. Classified in class 514, subclass 2.

Art Unit: 1632

VII. Claims 17-20 are drawn to a method for processing nucleocapsid protein monomer particle. Classified in class 530, and subclass 412.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-IV, and I are related as combination and subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (protein-protein, protein-nucleic acid, protein-carbohydrate, or protein-lipid) as claimed does not require the particulars of the subcombination as claimed because the other component in each instance could lend patentability to the combination. The subcombination has separate utility such as indicated in invention groups V-VII, respectively.

Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups V and VI are drawn to an *in vivo* method for stimulating an immune response, group VII is drawn to an *in vitro* method for preparation of a composition. Each of the groups differs either in the material (proteins or combination of nucleic acid and proteins) used in the process, the function of the process or the method steps (*in vivo* vs. *in vitro*). The different methods use material different

Art Unit: 1632

substances and reagents, have different method steps, different modes of operation, distinct technical considerations and search criteria.

Inventions VI and I, or V and II could be related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of group I could be used in the different process of groups VI and VII, etc., and the method of group V could be practiced with materially different products, such as a composition of group I.

Inventions VII and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of group II could be made with a different process, and the process of group VII could be used to make another materially different substance, such as a recombinant nucleocapsid protein monomers derived from human HBV.

The differences of the Inventions I-VII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

Art Unit: 1632

matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicants have elected (Paper #11) sequences ID Nos: 3-5, and cancer antigen as the first and second hapten for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Such species election applies to Invention groups I-VI if one of these groups is elected. Currently, claims 1-16 and 21-29 are generic.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1632

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
April 3, 2002



JAMES KETTER
PRIMARY EXAMINER